K061931

SOLARIS
Solaris Medical Technology, Inc.

JAN 31 2007

510(k) Summary

Submission Date:	23 June 2006
Submitter:	Solaris Medical Technology, Inc. 427 26th Avenue, Suite 101 San Francisco, CA 94121 USA
Submitter Contact:	Rachel Cheng, Director, Regulatory Affairs 415 221 2350 415 221 2360 (fax) rcheng@solarismedtech.com
Manufacturing Site:	Solaris Medical Technology, Inc. 6/F Building 9, 30th District, Keji Road Science Park, Nanshan District Shenzhen, Guangdong, 518057 CHINA
Official Contact:	Thomas Kroenke Principal Consultant Speed To Market, Inc. 2355 East Flamingo Road, Suite 201 G Las Vegas, NV 89119 USA tkroenke@speedtomarket.net 303 956 4232
Trade Name:	Solaris Compatible Reusable Adult SpO_2 Finger Sensors • Model S100A-090103 SpO2 Finger Sensor • Model S100A-300103 SpO2 Finger Sensor • Model S200A-090101 SpO2 Finger Sensor • Model S200A-300101 SpO2 Finger Sensor • Model S300A-300046 SpO2 Finger Sensor
Common Name:	Pulse Oximeter Sensor
Classification Name:	Oximeter
Classification Regulation:	21 CFR §870.2700
Product Code:	DQA

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Substantially Equivalent Devices:	***Solaris Model***	***Predicate 510(k) Number***	***Predicate Manufacturer / Model***
	S100A-090103 SpO_2 Finger Sensor	K993637*	Nellcor DS-100A SpO_2 Sensor, 0.9 m cable
	S100A-300103 SpO_2 Finger Sensor	K993637*	Nellcor DS-100A SpO_2 Sensor, 3.0 m cable
	S200A-090101 SpO_2 Finger Sensor	K030407*	BCI 3044 SpO_2 Sensor, 0.9 m cable
	S200A-300101 SpO_2 Finger Sensor	K030407*	BCI 3044 SpO_2 Sensor, 3.0 m cable
	S300A-300046 SpO_2 Finger Sensor	K962127*	Datex-Ohmeda OXY-F4-H SpO_2 Sensor, 3.0 m cable

* Please note these 510(k) numbers represent monitors containing a pulse oximetry module in which the predicate sensors were included as accessories.

Device Description: Solaris Compatible Reusable Adult SpO_2 Finger Sensors (Solaris Sensors) are compatible reusable sensors for use with major brands of patient monitors and oximeter devices.

Solaris Sensors are electro-optical sensors which function without skin penetration, electrical contact, or heat transfer. The sensors use optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the patient monitor or oximeter device. The sensor contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector. The LED and photodiode are contained in silicon rubber pads.

Intended Use: Solaris Sensors are indicated for use in continuous, non-invasive monitoring of arterial oxygen saturation and pulse rate for patients weighing more than 40 kg.

Technology Comparison: Solaris Sensors employ the same technological characteristics as the predicate devices to determine arterial oxygen saturation: arterially perfused tissue is illuminated sequentially by two wavelengths of LEDs, and the time varying absorbance of the tissue is measured by a photodetector.

This method is characteristic of all reusable sensors that are the subject of this submission as well as the predicate devices.

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Performance Testing:

Cleaning Instruction Testing	Solaris Sensors were tested in accordance with internal protocols to ensure that the cleaning instructions do not damage sensor labeling or degrade the material. Test results indicated that the cleaning instructions do not damage sensor labeling or degrade the material.
Biocompatibility Testing	Patient contact materials used in Solaris Sensors were tested in accordance with *ISO 10993-1: 2003, Biological evaluation of medical devices – Part 1: Evaluation and testing* for skin surface-contact, limited-duration devices. Test results indicated that the patient contact materials were non-toxic, non-sensitizing and non-irritating.
Electrical Safety Testing	Solaris Sensors were tested in accordance with *IEC 60601-1:1988; Am1: 1991; A2: 1995, Medical electrical equipment – Part 1: General requirements for safety*, Clauses 3, 5, 6, 48 and 56. Test results indicated that the sensors comply with the stated clauses.
Electromagnetic Compatibility Testing	Solaris Sensors were tested in accordance with *IEC 60601-1-2:2001, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests*, Clauses 5.1.1, 6.2.1 and 6.3.1. Test results indicated that the sensors comply with the stated clauses of the Standard.
Clinical Testing	Solaris Sensors were clinically tested to validate the performance and accuracy of the sensors under controlled hypoxia versus arterial oxygen saturation as determined by co-oximetry. All testing was performed under an institutionally approved protocol with subject informed consent. Test results indicated that the sensors meet the published specifications for accuracy over the 70 % – 100 % SpO_2 range.
Conclusion	Based upon a comparison of devices and performance testing results, Solaris Sensors are substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Solaris Medical Technology, Incorporated
C/O Mr. Thomas Kroenke
Principal Consultant
Speed to Market, Incorporated
2355 East Flamingo Road, Suite 201G
Las Vegas, Nevada 89119

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Re: K061931
Trade/Device Name: Solaris Compatible Reusable Adult SpO2 Finger Sensors Including: Model S100A-090103; Model S100A-300103; Model S200A-090101; Model S200A-300101; and Model S300A-300046
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 31, 2006
Received: January 3, 2007

Dear Mr. Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

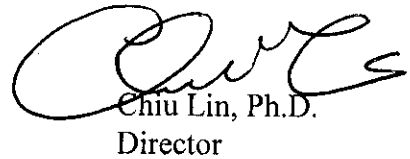
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: Solaris Compatible Reusable Adult SpO2 Finger Sensors including:

- Model S100A-090103;
- Model S100A-300103;
- Model S200A-090101;
- Model S200A-300101; and
- Model S300A-300046.

Indications for Use: Solaris Medical Technology, Inc. SpO_2 sensors are indicated for use in continuous, non-invasive monitoring of arterial oxygen saturation and pulse rate for patients weighing more than 40 kg.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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